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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,589	11/21/2001	Olivier Rousseaux	P67341US0	1439

136 7590 04/14/2003

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/926,589

Applicant(s)

ROUSSEAU ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***R sponse to Amendment***

The preliminary amendment filed 11/21/2001 has been entered. The specification has been amended to insert the 371 data. Claims 1-8 have been canceled. New claims 9-16 have been added. Consequently, claims 9-16 have been examined herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites "formula A" in line 2, but there is no formula labeled "A" in the claim. Thus, it is unclear if "A" is both of the formulae shown or one or the other of the formula. This is further made confusing because a dependent claim (claim 10) recites a formula A which is a substituent of the formula shown in claim 1. The formula which is being defined as "A" in claim 1 should be labeled accordingly.

Also in claim 9, in the second formula shown, one of the bonds in the DOTA backbone appears to be circled. It is unclear what is being signified thereby or if this is a printing or typographical error.

Claim 9 recites the limitation "the linear or branched or cyclic alkyl groups" in lines 14-15. There is insufficient antecedent basis for this limitation in the claim. The claim only previous recites "alkyl" in various locations, but not branched or cyclic. It is unclear what alkyl group is being defined by this recitation.

In claim 10, "or else R<sub>1</sub> is H..." is confusing because it is unclear what this is defining because R<sub>1</sub> is already previously defined to include H in line 5. It is unclear if this recitation is being used to define that when R<sub>1</sub> is H, R<sub>2</sub> must be formula A, as shown in claim 10.

Claim 13 depends on canceled claim 1 (recited in two locations) and therefore is indefinite for being dependent on a canceled claim.

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Claim 15 is indefinite because this claim is in independent form, but appears to be a dependent claim. For example, it states "Racemic compounds for which R is..." but there is nothing showing what R is so that it is clear what is being claimed. A compound cannot be defined by a substituent because it is unclear what the rest of the molecule includes. Further, Z is defined as a bond, but there is nothing for the bond to attach to in the claim. It is suggested that the claim is made to be a dependent claim, or the formula of claim 9 is added to the claim to clarify. Further, the recitation of "Racemic" is confusing because it is unclear what stereoisomers are present in the substituent as claimed.

Further, the print quality of the amendment adding claims 9-16 is poor, making it difficult to read some of the substituents (e.g., especially in the formula of claim 16). A clearer copy is requested.

The dependent claims fall therewith.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyer (US 6,187,285).

Meyer discloses a compound having a substituent R which is the same as that in claim 16 and therefore encompassed by claim 15, see columns 23-24, example 4. The recitation of "racemic" has not

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been given patentable weight as it appears in the preamble and because the claim, as in its present independent form, does not clearly define a racemic mixture.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (WO 97/01359, US equivalent 5,886,158 relied upon) in view of Uggeri (US 6,177,562).

Meyer discloses contrast agents having the formula set forth in columns 1-2 (i.e., DOTA analogues), which is the same as the claimed formula.

Meyer fails to specifically disclose a racemic mixture as claimed.

Uggeri discloses contrast agents having the formula set in column 3 (i.e., DOTA analogues) and teaches that racemic mixtures of such substituted DOTA analogues are useful as contrast agents for methods of MRI, see column 3, lines 42+ and example 2, column 22, lines 36-39.

It would have been obvious to one of ordinary skill in the art to prepare racemic mixtures of the contrast agents disclosed by Meyer because it is well known in the art that racemic mixtures of DOTA analogues are useful as contrast agents for MRI, as shown by Uggeri.

Claims 11-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (US 6,187,285) in view of Uggeri (US 6,177,562).

Meyer discloses a compound having a substituent R which is the same as that in claim 16 and therefore encompassed by claim 15, see columns 23-24, example 4.

Meyer fails to specifically disclose a racemic mixture as claimed.

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Uggeri discloses contrast agents having the formula set in column 3 (i.e., DOTA analogues) and teaches that racemic mixtures of such substituted DOTA analogues are useful as contrast agents for methods of MRI, see column 3, lines 42+ and example 2, column 22, lines 36-39.

It would have been obvious to one of ordinary skill in the art to prepare racemic mixtures of the contrast agents disclosed by Meyer because it is well known in the art that racemic mixtures of DOTA analogues are useful as contrast agents for MRI, as shown by Uggeri.

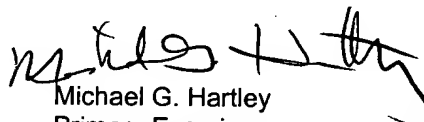
### **Conclusion**

No claims are allowed at this time. Claims 13-14 are free of the art of record because the prior art fails to teach or suggest the methods of preparing the racemic compounds as claimed, using the combination of pH, temperature and reaction as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
April 10, 2003